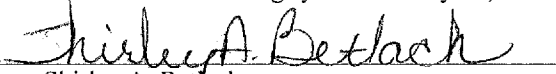


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Docket No.: 1023-234US01
Title: AUTOMATIC THERAPY ADJUSTMENTS

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via the United States Patent and Trademark Office electronic filing system on May 21, 2010.

By: 
Name: Shirley A. Betlach

APPEAL BRIEF

Board of Patent Appeals and Interferences
Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

This is an Appeal Brief in support of an appeal from the final Office Action dated December 28, 2009 finally rejecting claims 1, 5-19, 23-38 and 42-56, and the Advisory Action mailed on March 12, 2010 affirming the rejection of those claims. The Notice of Appeal was filed on March 26, 2010. The period for filing this Brief runs through May 26, 2010.

Please charge Deposit Account No. 50-1778 in the amount of \$540.00 for submission of this Appeal Brief, as required by 37 C.F.R. §41.27(a)(2) for a large entity. Please charge any additional fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

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REAL PARTY IN INTEREST

The Real Party in Interest is Medtronic, Inc. of Minneapolis, Minnesota.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences for the above-referenced patent application.

STATUS OF CLAIMS

Claims 1, 5–19, 23–38, and 42–56 are pending and are the subject of this Appeal. Claims 1, 5–19, 23–38, and 42–56 are set forth in Appendix A. Claims 49–54 were added by way of an Amendment filed on July 14, 2006. Claims 2–4, 20–22, and 39–41 were cancelled and claims 55 and 56 were added in an Amendment accompanying a Request for Continued Examination (RCE) filed on March 12, 2007.

Claims 1, 5–19, 23–38, and 42–56 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

STATUS OF AMENDMENTS

The claims on appeal are those submitted in the Amendment accompanying a Request for Continued Examination (RCE) filed on April 27, 2009. The non-final Office Action dated June 17, 2009 indicates that the Examiner entered the Amendment filed on April 27, 2009. No amendments were submitted after the non-final Office Action dated June 17, 2009, after the final Office Action dated December 28, 2009, or after the Advisory Action dated March 12, 2010.

SUMMARY OF CLAIMED SUBJECT MATTER

In general, Appellant's disclosure relates to techniques for providing automatic adjustments to a therapy.¹

Independent claim 1 is directed to a method comprising monitoring an output of a sensor,² the output of the sensor reflecting a physiological parameter of a patient,³ and initially defining an event based on the monitoring of the sensor output.⁴ Initially defining the event

¹ Appellant's disclosure at p. 1, ll. 27 and 28.

² *Id.* at page 9, ll. 9 and 10 and sensor 40 shown in FIG. 2.

³ *Id.* at page 9, ll. 10–12.

⁴ *Id.* at page 11, ll. 20–23.

comprises storing an indication of the monitored sensor output within a memory as the defined event.⁵ The method of claim 1 further comprises monitoring therapy delivered by a medical device⁶ while the output of the sensor was monitored during the event to initially define the event,⁷ generating therapy information based on the monitoring of the therapy while the output of the sensor was monitored during the event to initially define the event,⁸ associating the therapy information with the defined event within the memory,⁹ subsequently detecting the defined event by monitoring the output of the sensor¹⁰ and comparing the sensor output to the defined event,¹¹ and automatically providing therapy to the patient via the medical device according to the therapy information associated with the defined event in response to the detection.¹²

Independent claim 19 is directed to a medical device¹³ comprising a sensor¹⁴ that generates an output as a function of a physiological parameter of a patient,¹⁵ a therapy delivery module that delivers therapy to a patient,¹⁶ and a memory.¹⁷ The medical device further comprises a processor¹⁸ that monitors the output of the sensor,¹⁹ initially defines an event based on the monitoring of the sensor output by storing an indication of the monitored sensor output within the memory as the defined event,²⁰ monitors therapy delivered by the therapy delivery module device²¹ while the output of the sensor was monitored during the event to initially define the event,²² generates therapy information based on the monitoring of the therapy while the

⁵ *Id.*

⁶ *Id.* at page 8, ll. 1–9.

⁷ *Id.* at page 13, line 29 to page 14, line 2, at page 14, ll. 18–26, at page 15, ll. 18–21, and blocks 82, 84, and 86 shown in FIG. 6.

⁸ *Id.* at page 6, ll. 18 and 19, at page 7, ll. 24 and 25, at page 11, ll. 13–15, at page 14, ll. 23–25, and learned therapies 54 shown in FIG. 3.

⁹ *Id.* at page 13, ll. 27 and 28, and at page 14, ll. 23–26.

¹⁰ *Id.* at page 14, ll. 28–30.

¹¹ *Id.* at page 14, line 31 to page 15, line 4.

¹² *Id.* at page 15, ll. 7–12.

¹³ *Id.* at page 4, line 17, at page 6, ll. 1–9, implantable medical device (IMD) 12 shown in FIGS. 1 and 2, and programming device 20 shown in FIGS. 1 and 4.

¹⁴ *Id.* at page 9, ll. 9 and 10 and sensor 40 shown in FIG. 2.

¹⁵ *Id.* at page 9, ll. 10–12.

¹⁶ *Id.* at page 8, ll. 23–26 and therapy delivery circuit 32 shown in FIG. 2.

¹⁷ *Id.* at page 11, ll. 6–19 and memory 36 shown in FIGS. 1 and 3.

¹⁸ *Id.* at page 8, line 27 to page 9, line 11, and processor 34 shown in FIG. 2.

¹⁹ *Id.* at page 9, ll. 10–12.

²⁰ *Id.* at page 11, ll. 20–23.

²¹ *Id.* at page 8, ll. 1–9.

²² *Id.* at page 13, line 29 to page 14, line 2, at page 14, ll. 18–26, at page 15, ll. 18–21, and blocks 82, 84, and 86 shown in FIG. 6.

output of the sensor was monitored during the event to initially define the event,²³ associates the therapy information with the defined event within the memory,²⁴ subsequently detects the defined event by monitoring the output of the sensor²⁵ and comparing the sensor output to the defined event,²⁶ and automatically controls delivery of therapy to the patient by the therapy delivery module according to the therapy information associated with the defined event in response to the detection.²⁷

Independent claim 38 is directed to a computer-readable medium²⁸ comprising instructions²⁹ that cause a programmable processor to³⁰ monitor an output of a sensor,³¹ the output of the sensor reflecting a physiological parameter of a patient,³² and initially define an event based on the monitoring of the sensor output.³³ The instructions that cause the programmable processor to initially define the event comprise instructions that cause the programmable processor to store an indication of the monitored sensor output within a memory as the defined event.³⁴ The instructions further comprise instructions that cause the programmable processor to monitor therapy delivered by a medical device³⁵ while the output of the sensor was monitored during the event to initially define the event,³⁶ generate therapy information based on the monitoring of the therapy while the output of the sensor was monitored during the event to initially define the event,³⁷ associate the therapy information with the defined event within the memory,³⁸ subsequently detect the defined event by monitoring the output of the

²³ *Id.* at page 6, ll. 18 and 19, at page 7, ll. 24 and 25, at page 11, ll. 13–15, at page 14, ll. 23–25, and learned therapies 54 shown in FIG. 3.

²⁴ *Id.* at page 13, ll. 27 and 28, and at page 14, ll. 23–26.

²⁵ *Id.* at page 14, ll. 28–30.

²⁶ *Id.* at page 14, line 31 to page 15, line 4.

²⁷ *Id.* at page 15, ll. 7–12.

²⁸ *Id.* at page 11, ll. 2–5 and memory 36 shown in FIGS. 1 and 3.

²⁹ *Id.* at page 10, line 31 to page 11, line 2.

³⁰ *Id.* at page 10, line 31 to page 11, line 2, and processor 34 shown in FIGS. 2.

³¹ *Id.* at page 9, ll. 9 and 10 and sensor 40 shown in FIG. 2.

³² *Id.* at page 9, ll. 10–12.

³³ *Id.* at page 11, ll. 20–23.

³⁴ *Id.*

³⁵ *Id.* at page 8, ll. 1–9.

³⁶ *Id.* at page 13, line 29 to page 14, line 2, at page 14, ll. 18–26, at page 15, ll. 18–21, and blocks 82, 84, and 86 shown in FIG. 6.

³⁷ *Id.* at page 6, ll. 18 and 19, at page 7, ll. 24 and 25, at page 11, ll. 13–15, at page 14, ll. 23–25, and learned therapies 54 shown in FIG. 3.

³⁸ *Id.* at page 13, ll. 27 and 28, and at page 14, ll. 23–26.

sensor³⁹ and comparing the sensor output to the defined event,⁴⁰ and automatically control delivery of therapy to the patient via the medical device according to the therapy information associated with the defined event in response to the detection.⁴¹

Independent claim 56 is directed to a method comprising monitoring an output of a sensor,⁴² the output of the sensor reflecting a posture of a patient,⁴³ and initially defining a posture event based on the monitoring of the sensor output.⁴⁴ Initially defining the posture event comprises storing an indication of the monitored sensor output within a memory as the defined posture event.⁴⁵ The method of claim 56 further comprises monitoring therapy delivered by a medical device⁴⁶ while the output of the sensor was monitored during the event to initially define the event,⁴⁷ generating therapy information based on the monitoring of the therapy while the output of the sensor was monitored during the event to initially define the event,⁴⁸ associating the therapy information with the defined event within the memory,⁴⁹ subsequently detecting the defined posture event by monitoring the output of the sensor⁵⁰ and comparing the sensor output to the defined event,⁵¹ and providing therapy to the patient via the medical device according to the therapy information in response to the detection.⁵²

³⁹ *Id.* at page 14, ll. 28–30.

⁴⁰ *Id.* at page 14, line 31 to page 15, line 4.

⁴¹ *Id.* at page 15, ll. 7–12.

⁴² *Id.* at page 9, ll. 9 and 10, and sensor 40 shown in FIG. 2.

⁴³ *Id.* at page 9, line 21 to page 10, line 2, and activity/posture monitor 42 shown in FIG. 2.

⁴⁴ *Id.* at page 11, ll. 20–23.

⁴⁵ *Id.*

⁴⁶ *Id.* at page 8, ll. 1–9.

⁴⁷ *Id.* at page 13, line 29 to page 14, line 2, at page 14, ll. 18–26, at page 15, ll. 18–21, and blocks 82, 84, and 86 shown in FIG. 6.

⁴⁸ *Id.* at page 6, ll. 18 and 19, at page 7, ll. 24 and 25, at page 11, ll. 13–15, at page 14, ll. 23–25, and learned therapies 54 shown in FIG. 3.

⁴⁹ *Id.* at page 13, ll. 27 and 28, and at page 14, ll. 23–26.

⁵⁰ *Id.* at page 14, ll. 28–30.

⁵¹ *Id.* at page 14, line 31 to page 15, line 4.

⁵² *Id.* at page 15, ll. 7–12.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Appellant submits the following ground of rejection be reviewed on appeal: the rejection of claims 1, 5–19, 23–38, and 42–56 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

ARGUMENT

Appellant respectfully requests reversal of the rejection of claims 1, 5–19, 23–38, and 42–56 by the Board of Patent Appeals based on the arguments below. Appellant respectfully requests separate review of each set of claims argued under separate headings. For at least the reasons presented below, the Examiner has failed to establish that claims 1, 5–19, 23–38, and 42–56 do not comply with the written description requirement.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL – THE REJECTION OF CLAIMS 1, 5–19, 23–38, AND 42–56 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1, 5–19, 23–38, and 42–56 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. For at least the reasons discussed below, the rejection of claims 1, 5–19, 23–38, and 42–56 as failing to comply with the written description requirement is in error and should be reversed.

CLAIMS 1, 5–18, 49, 50, AND 55

In support of the rejection for independent claim 1, the Examiner alleged that the claim limitation of monitoring the therapy “while the output of the sensor was monitored,” as required by the independent claims, is not supported by the originally filed application.⁵³ The Examiner stated: “[a]lthough the portions of the disclosure cited by Applicant (e.g. par. 0035) appear to support defining an event (e.g., running) and monitoring therapy delivered by the device during the event and/or during the ‘learning mode,’ the Examiner was unable to find support for monitoring therapy while defining the event (i.e., monitoring the sensor).⁵⁴” The Examiner further stated: “[f]or instance, the patient could begin the ‘event’ (e.g., running) or initiate the learning mode; then the ‘event’ is defined based on monitoring the sensor; and *subsequently* the

⁵³ Final Office Action, dated December 28, 2009, page 2

⁵⁴ *Id.*

therapy is monitored by the device (as shown in Applicant's Figures 5 and 6).⁵⁵ The Examiner further stated that: "[t]hese figures lack, and the corresponding text is also deficient in describing, an embodiment wherein the 'initially defining' step occurs while 'monitoring therapy' (i.e., performed in parallel).⁵⁶"

The Examiner reasoned "[j]ust because these two acts are disclosed as occurring during the 'learning mode,' does not mean that one occurs 'while' the other occurs because both could occur in the learning mode (or while the patient is running), but at different times.⁵⁷" The Examiner concluded "[t]his appears to be an unsupported range of when the 'monitoring therapy' and 'monitoring the sensor' steps occur.⁵⁸"

The Examiner's conclusion that the features of claim 1 do not comply with the written description requirement is erroneous. The features of claim 1 are fully supported by Appellant's originally filed application. In particular, the feature "monitoring therapy delivered by a medical device while the output of the sensor was monitored during the event to initially define the event," recited in claim 1 is described by Appellant's disclosure in such a way as to convey to one skilled in the art that Appellant possessed the claimed invention at the time of filing.

Appellant notes that the written description requirement requires that Appellant demonstrate that he or she possessed the claimed invention at the time of filing, which is demonstrated by the specification.⁵⁹ To demonstrate that Appellant possessed the claimed invention, the specification need not provide exact recitation of the feature. The specification can demonstrate that Appellant possessed the invention through express, implicit, or inherent disclosure.⁶⁰

Paragraph [0062] is one example location within Appellant's specification that provides express and implicit support for "monitoring therapy delivered by a medical device while the output of the sensor was monitored," as required by claim 1. Paragraph [0062], which describes FIG. 6 of Appellant's application, states that "[p]rocessor 34 may record the sensor output or

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.* at pages 2 and 3.

⁵⁸ *Id.* at page 3.

⁵⁹ See MPEP 2163(I), citing *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319

⁶⁰ See MPEP 2163(I)(B) which states: "[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure."

information over any length of time, may record multiple samples, and may make the recording or recordings at any time after entering the learning mode. Processor 34 may store the recording(s), or the result of an analysis, e.g. feature, Fourier, or wavelet, or the recording(s) in memory 36 as an event 52. Processor 34 records therapy information as a learned therapy 54 during operation in the learning mode (84), and associates the learned therapy 54 with the defined event 52 (86), as described above with reference to FIG. 5.” (Emphasis added).

Paragraph [0062] makes clear that sensor output or information is recorded at any time and over any length of time after entering the learning mode. “Any length of time” necessarily includes the entire time, i.e., the entire duration of the learning mode. According to paragraph [0062], monitoring of the delivered therapy also occurs during operation in the learning mode. Thus, paragraph [0062] supports examples in which the monitoring of the sensor output and the monitoring of the delivered therapy occur in parallel in the learning mode.

In other words, if monitoring of the sensor output can occur any time and over any length time in the learning mode, and monitoring of the delivered therapy occurs in the learning mode, then, at least implicitly, paragraph [0062] supports monitoring therapy delivered by a medical device while the output of the sensor was monitored. Accordingly, paragraph [0062] demonstrates that Appellant possessed the claimed feature of “monitoring therapy delivered by a medical device while the output of the sensor was monitored during the event to initially define the event,” recited in claim 1.

Furthermore, a determination of whether the specification meets the written description requirement is based on the knowledge of one of skill in the art.⁶¹ Appellant respectfully submits that one of ordinary skill in the art, upon referencing paragraph [0062], as well as, the entirety of the specification, would recognize that Appellant possessed the features of the claims.

As another example, paragraph [0035] states “[p]atient 14 may...simply begin running and allow IMD 12 to record an exemplar of the sensor output while patient 14 is running...[w]hile patient 14 is running...patient 14 uses programming device 20, e.g., keypad 24, to change one or more stimulation parameters in an attempt to maintain adequate symptom control during the activity.” Paragraph [0059] states “patient 14 adjusts stimulation parameters

⁶¹ See MPEP 2163(II)(A) which states: “[t]he analysis of whether the specification complies with written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed.”

over a period of time after directing IMD 12 to enter the learning mode, e.g., during the event...so that IMD 12 learns appropriate adjustments to therapy to provide while patient 14 is running, and may adjust stimulation parameters while running to maintain effective and comfortable neurostimulation therapy.” (Emphasis added). Paragraph [0066] goes on to state “[f]or example, an event 52 may be patient 14 running, and the learned therapy 54 may include changes to stimulation parameters occurring at associated times during the “running” event such that effective and comfortable therapy is maintained.”

Initially defining the event comprises monitoring the sensor output for some period of time, and storing an indication of the monitored sensor output during that period of time as the defined event. It is clear from the cited paragraphs that the monitoring of the therapy may occur during the event, i.e., during the period of time in which the sensor output was monitored, so that an IMD or other device learns appropriate adjustments to therapy to provide during the event (when subsequently detected) to maintain effective and comfortable neurostimulation therapy.

Moreover, one of ordinary skill in the art would have read Appellant’s specification to disclose that, in at least one example, monitoring therapy delivered by a medical device would occur while the output of the sensor was monitored to provide some possible, non-limiting advantages. For example, paragraph [0011] describes that a possible advantage is to provide a medical device that can “provide therapy that better addresses changes in the symptoms of a patient and/or level of efficacy or side effects of the therapy associated with an activity undertaken by the patient.” (Emphasis added). One of ordinary skill in the art would understand that monitoring for therapy changes during the definition of the event, rather than after the event had been defined and may have ended, would have facilitated addressing changes in symptoms during a subsequent occurrence the event.

The Examiner is incorrect in stating that the specification only provides support for the act of monitoring therapy and the act of monitoring the sensor output happening at different times. In fact, for all the reasons described above, one of ordinary skill in the art would have read Appellant’s disclosure in such a manner that the act of monitoring therapy and the act of monitoring the sensor output would have occurred at the same time, or at least overlapped in time.

For at least all the reasons advanced above, Appellant’s disclosure conveys to one of ordinary skill in the art that the inventor(s) possessed the claimed invention at the time of filing.

Appellant respectfully requests reversal of the rejections under 35 U.S.C. § 112, first paragraph for claim 1. Claims 5–18, 49, 50, and 55 depend upon claim 1. Since the 35 U.S.C. § 112, first paragraph rejection is improper for claim 1, the 35 U.S.C. § 112, first paragraph rejection for claims 5–18, 49, 50, and 55 is improper. Appellant respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, first paragraph for claims 5–18, 49, 50, and 55.

CLAIMS 19, 23–37, 51, AND 52

Claims 19, 23–37, 51, and 52 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In support of the rejection, the Examiner rejected independent claim 19 for reasons substantially similar to those described above with respect to claim 1.

For example, although not specifically recited in the Final Office Action dated December 28, 2009, the Examiner seemed to allege that a processor that “monitors therapy delivered by the therapy delivery module device while the output of the sensor was monitored during the event to initially define the event,” is not disclosed in Appellant’s specification.

Contrary to the Examiner’s allegations, as described above, paragraphs [0062], [0035], [0059], [0066], and [0011] when taken either alone or together, clearly demonstrate that Appellant possessed the above-recited feature of claim 19. For example, Appellant’s specification makes clear that sensor output is recorded at any time and over any length of time during operation in the learning mode. Also, Appellant’s specification makes clear that the monitoring of delivered therapy also occurs during that length of time, e.g., during operation in the learning mode. Therefore, one of ordinary skill in the art would have read Appellant’s disclosure in such a manner that the processor monitors therapy delivered by the therapy delivery module device, at the same time, or at least overlapped in time, while the output of the sensor was monitored during the event to initially define the event.

For at least all the reasons advanced above, Appellant’s disclosure conveys to one of ordinary skill in the art that the inventor(s) possessed the claimed invention at the time of filing. Appellant respectfully requests reversal of the rejections under 35 U.S.C. § 112, first paragraph for claim 19. Claims 23–37, 51, and 52 depend upon claim 19. Since the 35 U.S.C. § 112, first paragraph rejection is improper for claim 19, the 35 U.S.C. § 112, first paragraph rejection for

claims 23–37, 51, and 52 is improper. Appellant respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, first paragraph for claims 23–37, 51, and 52.

CLAIMS 38, 42–48, 53, AND 54

Claims 38, 42–48, 53, and 54 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In support of the rejection, the Examiner rejected independent claim 38 for reasons substantially similar to those described above with respect to claims 1 and 19.

For example, although not specifically recited in the Final Office Action dated December 28, 2009, the Examiner seemed to allege that instructions on a computer-readable storage medium that cause a programmable processor to “monitor therapy delivered by a medical device while the output of the sensor was monitored during the event to initially define the event,” is not disclosed in Appellant’s specification.

Again, as described above, paragraphs [0062], [0035], [0059], [0066], and [0011] when taken either alone or together, clearly demonstrate that Appellant possessed the above-recited feature of claim 38. Appellant respectfully submits that one of ordinary skill in the art would have read Appellant’s disclosure in such a manner that the computer-readable medium comprises instructions that cause the programmable processor to monitor therapy delivered by a medical device, at the same time, or at least overlapped in time, while the output of the sensor was monitored during the event to initially define the event.

For at least all the reasons advanced above, Appellant’s disclosure conveys to one of ordinary skill in the art that the inventor(s) possessed the claimed invention at the time of filing. Appellant respectfully requests reversal of the rejections under 35 U.S.C. § 112, first paragraph for claim 38. Claims 42–48, 53, and 54 depend upon claim 38. Since the 35 U.S.C. § 112, first paragraph rejection is improper for claim 38, the 35 U.S.C. § 112, first paragraph rejection for claims 42–48, 53, and 54 is improper. Appellant respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, first paragraph for claims 42–48, 53, and 54.

CLAIM 56

Claim 56 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In support of the rejection, the Examiner

rejected independent claim 56 for reasons substantially similar to those described above with respect to claims 1, 19, and 38.

For example, although not specifically recited in the Final Office Action dated December 28, 2009, the Examiner seemed to allege that the feature “monitoring therapy delivered by a medical device while the output of the sensor was monitored during the event to initially define the event,” is not disclosed in Appellant’s specification.

Again, as described above, paragraphs [0062], [0035], [0059], [0066], and [0011] when taken either alone or together, clearly demonstrate that Appellant possessed the above-recited feature of claim 56. Appellant respectfully submits that one of ordinary skill in the art would have read Appellant’s disclosure in such a manner that monitoring therapy delivered by a medical device occurred at the same time, or at least overlapped in time, while the output of the sensor was monitored during the event to initially define the event.

For at least all the reasons advanced above, Appellant’s disclosure conveys to one of ordinary skill in the art that the inventor(s) possessed the claimed invention at the time of filing. Appellant respectfully requests reversal of the rejections under 35 U.S.C. § 112, first paragraph for claim 56.

CONCLUSION

The Examiner has failed to meet the burden of establishing nonpatentability of Appellant’s claims 1, 5–19, 23–38, and 42–56. Appellant respectfully requests review of the rejections addressed above, and reversal of all pending rejections. Appellant respectfully requests separate review by the Board for each set of claims argued under separate headings.

Date:

May 21, 2010

By:

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APPENDIX A
THE CLAIMS ON APPEAL

1. A method comprising:

monitoring an output of a sensor, the output of the sensor reflecting a physiological parameter of a patient;

initially defining an event based on the monitoring of the sensor output, wherein initially defining the event comprises storing an indication of the monitored sensor output within a memory as the defined event;

monitoring therapy delivered by a medical device while the output of the sensor was monitored during the event to initially define the event;

generating therapy information based on the monitoring of the therapy while the output of the sensor was monitored during the event to initially define the event;

associating the therapy information with the defined event within the memory;

subsequently detecting the defined event by monitoring the output of the sensor and comparing the sensor output to the defined event; and

automatically providing therapy to the patient via the medical device according to the therapy information associated with the defined event in response to the detection.

5. The method of claim 1, wherein the sensor comprises an accelerometer.

6. The method of claim 1, wherein the sensor output reflects at least one of motion or posture of the patient.

7. The method of claim 1, wherein defining the event based on the monitoring of the sensor output comprises recording the sensor output over a period of time.
8. The method of claim 1, wherein generating therapy information comprises recording a value of a therapy parameter that controls delivery of therapy by the medical device.
9. The method of claim 8, wherein recording the value of the therapy parameter comprises recording a change to the therapy parameter made by the user.
10. The method of claim 9, wherein recording a change to the therapy parameter comprises recording changes to the therapy parameter made by the user over a period of time.
11. The method of claim 10, wherein providing therapy to a patient according to the therapy information comprises changing the therapy parameter at a time subsequent to detection of the event according to the recorded changes to the therapy parameter.
12. The method of claim 9, wherein the medical device includes an implantable medical device, and recording the change to the therapy parameter comprises receiving the change to the therapy parameter made by the user via a programming device.

13. The method of claim 12, wherein the implantable medical device includes an implantable neurostimulator, and receiving the change to the therapy parameter comprises receiving a change to at least one of a pulse amplitude, a pulse width, or a pulse rate of stimulation energy delivered by the neurostimulator.

14. The method of claim 8, wherein recording the value of the parameter comprises receiving the value of the parameter and a time from a user, and providing therapy to a patient according to the therapy information comprises changing delivery of therapy at a time subsequent to detection of the event according to the value and time received from the user.

15. The method of claim 1, wherein providing therapy to a patient according to the therapy information comprises suspending delivery of therapy.

16. The method of claim 1, further comprising presenting the defined event to a clinician as diagnostic data.

17. The method of claim 16, wherein presenting the defined event to the clinician comprises presenting the defined event as a marker within a timing diagram.

18. The method of claim 1, further comprising receiving a command from a user to enter a learning mode in order to define the event and record and associate therapy information with the defined event, wherein the user is one of a clinician or the patient.

19. A medical device comprising:

a sensor that generates an output as a function of a physiological parameter of a patient;

a therapy delivery module that delivers therapy to a patient;

a memory; and

a processor that:

monitors the output of the sensor;

initially defines an event based on the monitoring of the sensor output by storing an indication of the monitored sensor output within the memory as the defined event;

monitors therapy delivered by the therapy delivery module device while the output of the sensor was monitored during the event to initially define the event;

generates therapy information based on the monitoring of the therapy while the output of the sensor was monitored during the event to initially define the event;

associates the therapy information with the defined event within the memory;

subsequently detects the defined event by monitoring the output of the sensor and comparing the sensor output to the defined event; and

automatically controls delivery of therapy to the patient by the therapy delivery module according to the therapy information associated with the defined event in response to the detection.

23. The medical device of claim 19, wherein the sensor output reflects at least one of motion or posture of the patient.

24. The medical device of claim 19, wherein the sensor comprises an accelerometer.

25. The medical device of claim 24, wherein the accelerometer comprises a multi-axis accelerometer.

26. The medical device of claim 19, wherein the processor defines the event by storing a recording of the sensor output over a period of time within the memory.

27. The medical device of claim 19, wherein the therapy information comprises a value of a parameter that controls delivery of therapy to the patient, and the processor associates the value and the defined event within the memory.

28. The medical device of claim 27, wherein the therapy information reflects a change to the parameter made by a user, and the processor records the change and associates the recorded change with the defined event within the memory.

29. The medical device of claim 28, wherein the therapy information reflects changes to the parameter made by the user over a period of time, and the processor records the changes over the period of time and associates the recorded changes with the defined event within the memory.

30. The medical device of claim 29, wherein the processor changes the therapy parameter at a time subsequent to detection of the event according to the recorded changes to the therapy parameter.

31. The medical device of claim 27, wherein the processor receives the value of the parameter and a time from a user via a user interface, and changes delivery of therapy at a time subsequent to detection of the event according to the value and time received from the user.

32. The medical device of claim 19, wherein the processor stores the defined event within the memory as diagnostic data for presentation to a clinician.

33. The medical device of claim 32, further comprising a user interface, wherein the processor presents the defined event to the clinician as a marker within a timing diagram via the user interface.

34. The medical device of claim 19, wherein the processor suspends delivery of therapy in response to the detection of the previously defined event.

35. The medical device of claim 19, wherein the medical device comprises an implantable neurostimulator.

36. The medical device of claim 19, wherein the medical device comprises a programming device that communicates with an implantable medical device.

37. The medical device of claim 19, wherein the processor receives a command from a user to enter a learning mode in order to define the event and record and associate therapy information with the defined event, and wherein the user comprises one of a clinician or the patient.

38. A computer-readable medium comprising instructions that cause a programmable processor to:

monitor an output of a sensor, the output of the sensor reflecting a physiological parameter of a patient;

initially define an event based on the monitoring of the sensor output, wherein the instructions that cause the programmable processor to initially define the event comprise instructions that cause the programmable processor to store an indication of the monitored sensor output within a memory as the defined event;

monitor therapy delivered by a medical device while the output of the sensor was monitored during the event to initially define the event;

generate therapy information based on the monitoring of the therapy while the output of the sensor was monitored during the event to initially define the event;

associate the therapy information with the defined event within the memory;

subsequently detect the defined event by monitoring the output of the sensor and comparing the sensor output to the defined event; and

automatically control delivery of therapy to the patient via the medical device according to the therapy information associated with the defined event in response to the detection.

42. The computer-readable medium of claim 38, wherein the instructions that cause the programmable processor to define the event based on the monitoring of the sensor output comprise instructions that cause the programmable processor to record the sensor output over a period of time.

43. The computer-readable medium of claim 38, wherein the instructions that cause the programmable processor to generate therapy information comprise instructions that cause the processor to record a value of a parameter that controls delivery of therapy by the therapy device.

44. The computer-readable medium of claim 43, wherein the instructions that cause the programmable processor to record a value of a therapy parameter comprises instructions that cause the programmable processor to record a change to the parameter made by the user.

45. The computer-readable medium of claim 44, wherein the instructions that cause the programmable processor to record a change to the parameter comprises instructions that cause the programmable processor to record changes to the therapy parameter made by the user over a period of time.

46. The computer-readable medium of claim 45, wherein the instructions that cause the programmable processor to provide therapy to a patient according to the therapy information comprise instructions that cause the programmable processor to change the therapy parameter at a time subsequent to detection of the event according to the recorded changes to the therapy parameter.

47. The computer-readable medium of claim 43, wherein the instructions that cause the programmable processor to record a value of a parameter comprise instructions that cause the programmable processor to receive the value of the parameter and a time from the user, and the instructions that cause the programmable processor to provide therapy to a patient according to the therapy information comprise instructions that cause the programmable processor to change delivery of therapy at a time subsequent to detection of the event according to the value and time received from the user.

48. The computer-readable medium of claim 38, wherein the instructions cause the processor to receive a command from a user to enter a learning mode in order to define the event and record and associate therapy information with the defined event, and wherein the user is one of a clinician or the patient.

49. The method of claim 1, further comprising receiving a command from a user to enter a learning mode in order to define the event and associate the therapy information with the defined event.

50. The method of claim 1, wherein providing therapy comprises managing pain in the patient.

51. The medical device of claim 19, further comprising a user interface, wherein the processor receives a command to enter a learning mode from a user via the user interface in order to define the event and associate the therapy information with the defined event.

52. The medical device of claim 19, further comprising a pulse generator that is controlled by the processor to deliver pain management therapy to the patient.

53. The computer readable medium of claim 38, wherein the instructions cause the processor to receive a command from a user to enter a learning mode in order to define the event and associate the therapy information with the defined event.

54. The computer readable medium of claim 38, wherein the instructions that cause the processor to provide therapy comprise instructions that cause the processor to control a pulse generator to deliver pain management therapy to the patient.

55. The method of claim 1, further comprising performing each of the following by the medical device:

monitoring the output of the sensor;

initially defining the event based on the monitoring of the sensor output, wherein initially defining the event comprises storing an indication of the monitored sensor output within a memory as the defined event;

monitoring therapy delivered by the medical device while the output of the sensor was monitored during the event to initially define the event;

generating therapy information based on the monitoring of the therapy while the output of the sensor was monitored during the event to initially define the event;

associating the therapy information with the defined event within the memory;

subsequently detecting the defined event; and

providing therapy to the patient via the medical device according to the therapy information in response to the detection.

56. A method comprising:

monitoring an output of a sensor, the output of the sensor reflecting a posture of a patient;
initially defining a posture event based on the monitoring of the sensor output, wherein
initially defining the posture event comprises storing an indication of the monitored sensor
output within a memory as the defined posture event;

monitoring therapy delivered by a medical device while the output of the sensor was
monitored during the event to initially define the event;

generating therapy information based on the monitoring of the therapy while the output
of the sensor was monitored during the event to initially define the event;

associating the therapy information with the defined event within the memory;

subsequently detecting the defined posture event by monitoring the output of the sensor
and comparing the sensor output to the defined event; and

providing therapy to the patient via the medical device according to the therapy
information in response to the detection.

APPENDIX B
EVIDENCE

None.

APPENDIX C
RELATED PROCEEDINGS

None.